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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,693	09/12/2005	Ben Adler	I-2002.011 US	8800

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INTERVET INC.
PATENT DEPARTMENT
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EXAMINER	
GANGLE, BRIAN J	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,693	ADLER ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-8,19-22 and 24-47* is/are pending in the application.

4a) Of the above claim(s) *5-8,19-22,25-28,31,32 and 34-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,29,30 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/18/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group VII in the response filed 11/13/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Newly submitted claims 46-47 are directed to an invention that is independent or distinct from the invention originally claimed for the reasons set forth in the original restriction requirement. As outlined previously, the technical features linking the inventions does not constitute a special technical feature as defined by PCT Rule 13.2, as they do not define a contribution over the art (see Joens *et al.*, Infect. Immun., 54:893-896, 1986).

Claims 5-8, 19-22, and 24-47 are pending. Claims 5-8, 19-22, 25-28, 31-32, and 34-47 are withdrawn as being drawn to non-elected inventions. Claims 24, 29-30, and 33 are currently under examination.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See, for example, pages 5, 12, and 17. It should be noted that the cited occurrences of improper use are only exemplary and applicant should review the specification to correct any other use of hyperlinks.

The use of the trademarks pBluescript and Tween have been noted on pages 28 and 31, respectively, in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It should be noted that the cited occurrences of improper use are only exemplary and applicant should review the specification to correct any other use of trademarks.

Information Disclosure Statement

The information disclosure statement filed 1/18/2005 has been considered. An initialed copy is enclosed.

Claim Objections

Claims 24 and 29 are objected to because of the following informalities: the claims contain the acronym SDS-PAGE. While acronyms are permissible shorthand in the claims, the first recitation should include the full recitation followed by the acronym in parentheses. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 29, and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The claims are drawn to a diagnostic kit for detecting *Brachyspira hyodysenteriae* antibodies, comprising an immunogenic 61 kD *Brachyspira hyodysenteriae* lipoprotein or antigenic fragment thereof; an isolated and purified immunogenic *Brachyspira hyodysenteriae*

lipoprotein of 61 kD; and an immunogenic composition comprising an immunogenically effective amount of an isolated and purified immunogenic *Brachyspira hyodysenteriae* lipoprotein of 61 kD, and a pharmaceutically acceptable carrier. The use of the term "an" in claims 24 and 29 suggests that there are 61 kD lipoproteins, other than SEQ ID NO:2, which meet the limitations of the claims. Therefore, the claims are drawn to *any* 61 kD lipoprotein from *Brachyspira hyodysenteriae*, or antigenic fragments thereof.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. To adequately describe the genus of antigenic fragments, applicant must adequately describe the antigenic determinants (immunoepitopes) that allow the detection of antibodies directed against *Brachyspira hyodysenteriae*. The specification discloses SEQ ID NO:2, which meets the written description requirements, but does not show that antigenic fragments thereof would be capable of allowing detection of antibodies directed against *Brachyspira hyodysenteriae*; nor does the specification disclose any other 61 kD lipoproteins that are capable of allowing detection of antibodies directed against *Brachyspira hyodysenteriae*. The specification further does not disclose distinguishing and identifying features of a representative number of members of the genus of antigenic fragments to which the claims are drawn, such as a correlation between the structure of the immunoepitope and its recited function (i.e. detecting antibodies directed against *Brachyspira hyodysenteriae*), so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus of antigenic fragments. Moreover, the specification fails to disclose which amino acid residues are essential to the function of the immunoepitope or which amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent, or by which other amino acids the essential amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent. Therefore, since the specification fails to adequately describe at least a substantial number of members of the genus of immunoepitopes

to which the claims are based; the specification fails to adequately describe at least a substantial number of members of the claimed genus of antigenic fragments capable of detecting antibodies directed against *Brachyspira hyodysenteriae*.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description'' Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical

formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

The *Guidelines* further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. As evidenced by Greenspan *et al.* (*Nature Biotechnology* 7: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan *et al.* recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan *et al.*, an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of immunoepitopes, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of antigenic fragments capable of detecting antibodies directed against *Brachyspira hyodysenteriae*. Therefore, because the art is unpredictable, in accordance with the *Guidelines*, the description of immunoepitopes (antigenic determinants) is not deemed representative of the genus of antigenic fragments to which the claim refers. Hence, only SEQ ID NO:2 meets the written description requirements.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a diagnostic kit for detecting antibodies directed against a 61 kD *Brachyspira hyodysenteriae* lipoprotein, comprising an immunogenic 61 kD *Brachyspira hyodysenteriae* lipoprotein, does not reasonably provide enablement for the claim as drawn. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claim is drawn to a diagnostic kit for detecting *Brachyspira hyodysenteriae*

antibodies, comprising an immunogenic 61 kD *Brachyspira hyodysenteriae* lipoprotein or antigenic fragment thereof. The claimed kit encompasses any fragment of said 61 kD lipoprotein that is antigenic, and must be capable of detecting any antibody directed against *Brachyspira hyodysenteriae*, including antibodies directed against components of *Brachyspira hyodysenteriae* other than the 61 kD lipoprotein.

The specification discloses a 61 kD *Brachyspira hyodysenteriae* lipoprotein with the sequence of SEQ ID NO:2. Said lipoprotein would be capable of detecting antibodies directed against itself. The specification does not disclose any fragments of said protein which are capable of detecting any antibody directed against *Brachyspira hyodysenteriae*, including antibodies directed against components of *Brachyspira hyodysenteriae* other than the 61 kD lipoprotein.

While the skill in the art of immunology is high, to date, prediction of a specific immune response for any given composition in any given animal is quite unpredictable. Moreover, protein chemistry is probably one of the most unpredictable areas of biotechnology. Consequently, the effects of sequence dissimilarities upon protein structure and function cannot be predicted. Bowie *et al.* (Science, 1990, 247:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function, carry out the instructions of the genome **and form immunoepitopes**. Bowie *et al.* further teach that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (column 1, page 1306). Bowie *et al.* further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (column 2, page 1306). Additionally, as evidenced by Greenspan *et al.* (*Nature Biotechnology* 7: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan *et al.* recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2).

According to Greenspan *et al.*, an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows that the immunoepitopes that would allow the detection of antibodies directed against *Brachyspira hyodysenteriae* can only be identified empirically. This constitutes undue experimentation. Therefore, given the lack of success in the art, the lack of working examples commensurate in scope to the claimed invention and the unpredictability of the generation of antibodies to a particular epitope, the specification, as filed, does not provide enablement for the full scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is rendered vague and indefinite by the phrase "detecting *Brachyspira hyodysenteriae* antibodies." Bacteria do not produce antibodies. It is assumed that applicant is referring to anti-*Brachyspira hyodysenteriae* antibodies, or to antibodies directed against *Brachyspira hyodysenteriae*.

Claim 33 is rendered vague and indefinite by the phrase "immunogenically effective amount." It is not clear what limitations are engendered by this term. The claimed protein is either immunogenic or not. What type of efficacy does applicant intend there to be? Does applicant intend for there to be a certain magnitude or type of immune response for which there must be a sufficient quantity of protein?

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24, 29-30, and 33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Thomas *et al.* (Infect. Immun., 60:3111-3116, 1992; IDS filed 1/18/2005).

The instant claims are drawn to a diagnostic kit for detecting *Brachyspira hyodysenteriae* antibodies, comprising an immunogenic 61 kD *Brachyspira hyodysenteriae* lipoprotein, as measured by SDS-PAGE, or antigenic fragment thereof (claim 24); an isolated and purified immunogenic *Brachyspira hyodysenteriae* lipoprotein of 61 kD, as measured by SDS-PAGE (claim 29); wherein the lipoprotein has the amino acid sequence of SEQ ID NO:2 (claim 30); and an immunogenic composition comprising an immunogenically effective amount of a 61 kD *Brachyspira hyodysenteriae* lipoprotein and an acceptable pharmaceutical carrier (claim 33).

Thomas *et al.* disclose a 60kD protein isolated from the detergent phase extraction of *Brachyspira hyodysenteriae* cell membranes (see figure 1 and page 3113, column 1, paragraph

2). Said protein was also found to incorporate a radioactive fatty acid label, showing the lipid nature of the protein (page 3113, column 2, paragraph 1). Thomas *et al.* further disclose said protein suspended in phosphate-buffered saline, which is a pharmaceutically acceptable carrier (see page 3112, column 1, paragraph 2). Due to the fact that the claimed lipoprotein is found naturally in *Brachyspira hyodysenteriae*, and to the similarity in molecular weight between the claimed protein and the protein disclosed by Thomas *et al.*, it is deemed, in the absence of evidence to the contrary that the two proteins are the same. Thomas *et al.* anticipates the claimed invention because the identification of a new characteristic (i.e. the amino acid sequence) does not make that product patentable (see MPEP 2112 R-3). Regarding claim 24, it would have been obvious to one of ordinary skill in the art to package said protein in a kit for ease of use.

Claims 24, 29-30, and 33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chatfield *et al.* (Infect. Immun., 56:1070-1075, 1988; IDS filed 1/18/2005).

The instant claims are drawn to a diagnostic kit for detecting *Brachyspira hyodysenteriae* antibodies, comprising an immunogenic 61 kD *Brachyspira hyodysenteriae* lipoprotein, as measured by SDS-PAGE, or antigenic fragment thereof (claim 24); an isolated and purified immunogenic *Brachyspira hyodysenteriae* lipoprotein of 61 kD, as measured by SDS-PAGE (claim 29); wherein the lipoprotein has the amino acid sequence of SEQ ID NO:2 (claim 30); and an immunogenic composition comprising an immunogenically effective amount of a 61 kD *Brachyspira hyodysenteriae* lipoprotein and an acceptable pharmaceutical carrier (claim 33).

Chatfield *et al.* disclose a 61 kD SDS-soluble protein isolated from *Treponema* (now *Brachyspira*) *hyodysenteriae* (Figures 5 and 6). Due to the fact that the claimed lipoprotein is found naturally in *Brachyspira hyodysenteriae*, and to the similarity in molecular weight between the claimed protein and the protein disclosed by Chatfield *et al.*, it is deemed, in the absence of evidence to the contrary that the two proteins are the same. Chatfield *et al.* anticipates the claimed invention because the identification of a new characteristic (i.e. the amino acid sequence) does not make that product patentable (see MPEP 2112 R-3). Regarding claim 24, it would have been obvious to one of ordinary skill in the art to package said protein in a kit for ease of use.

Claims 24, 29-30, and 33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wannemuehler *et al.* (Infect. Immun., 56:3032-3039, 1988; IDS filed 1/18/2005).

The instant claims are drawn to a diagnostic kit for detecting *Brachyspira hyodysenteriae* antibodies, comprising an immunogenic 61 kD *Brachyspira hyodysenteriae* lipoprotein, as measured by SDS-PAGE, or antigenic fragment thereof (claim 24); an isolated and purified immunogenic *Brachyspira hyodysenteriae* lipoprotein of 61 kD, as measured by SDS-PAGE (claim 29); wherein the lipoprotein has the amino acid sequence of SEQ ID NO:2 (claim 30); and an immunogenic composition comprising an immunogenically effective amount of a 61 kD *Brachyspira hyodysenteriae* lipoprotein and an acceptable pharmaceutical carrier (claim 33).

Wannemuehler *et al.* disclose a 61 kD protein isolated from a detergent phase extraction of *Brachyspira hyodysenteriae* cell membranes (Figure 1). Due to the fact that the claimed lipoprotein is found naturally in *Brachyspira hyodysenteriae*, and to the similarity in molecular weight between the claimed protein and the protein disclosed by Wannemuehler *et al.*, it is deemed, in the absence of evidence to the contrary that the two proteins are the same. Wannemuehler *et al.* anticipates the claimed invention because the identification of a new characteristic (i.e. the amino acid sequence) does not make that product patentable (see MPEP 2112 R-3). Regarding claim 24, it would have been obvious to one of ordinary skill in the art to package said protein in a kit for ease of use.

Claims 24, 29-30, and 33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Joens *et al.* (Infect. Immun., 54:893-896, 1986; cited in the restriction requirement filed 9/28/2006).

The instant claims are drawn to a diagnostic kit for detecting *Brachyspira hyodysenteriae* antibodies, comprising an immunogenic 61 kD *Brachyspira hyodysenteriae* lipoprotein, as measured by SDS-PAGE, or antigenic fragment thereof (claim 24); an isolated and purified immunogenic *Brachyspira hyodysenteriae* lipoprotein of 61 kD, as measured by SDS-PAGE (claim 29); wherein the lipoprotein has the amino acid sequence of SEQ ID NO:2 (claim 30); and

an immunogenic composition comprising an immunogenically effective amount of a 61 kD *Brachyspira hyodysenteriae* lipoprotein and an acceptable pharmaceutical carrier (claim 33).

Joens *et al.* disclose a 59 kD protein isolated from *Brachyspira hyodysenteriae* (Figure 1). Due to the fact that the claimed lipoprotein is found naturally in *Brachyspira hyodysenteriae*, and to the similarity in molecular weight between the claimed protein and the protein disclosed by Joens *et al.*, it is deemed, in the absence of evidence to the contrary that the two proteins are the same. Joens *et al.* anticipates the claimed invention because the identification of a new characteristic (i.e. the amino acid sequence) does not make that product patentable (see MPEP 2112 R-3). Regarding claim 24, it would have been obvious to one of ordinary skill in the art to package said protein in a kit for ease of use.

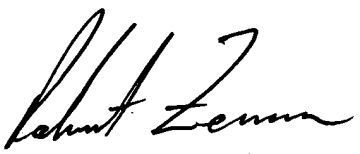
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian Gangle
AU 1645



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